

Technical Expert Panel (TEP) Charter

Project Title: ESRD Mineral and Bone Disorder Measure Development

TEP Expected Time Commitment and Dates:

The call for nominations period opened on November 3rd and closes on November 17th 2023

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop facility-level measures in the area of mineral and bone disorder. The contract number is 75FCMC18D0041, task order number 75FCMC23F0001. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Project Objectives:

UM-KECC has been tasked by CMS to develop dialysis facility quality measures that evaluate the effectiveness of mineral and bone disorder (MBD) management as part of the treatment of end-stage renal disease (ESRD) among US dialysis facilities.

Technical Expert Panel (TEP) Objectives:

The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of a draft measure that addresses potentially important quality gaps in mineral and bone disorder management. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Specifically, the TEP will engage in discussion to develop potential quality measures that could incentivize the best practice of MBD management given the lack of high quality evidence to guide specific therapies (e.g. nutritional, pharmacologic, surgical). TEP input will be sought regarding potential sources of data such as the EQRS system and Medicare claims that may provide useful information about MBD diagnoses, diagnostic testing, medication use, and procedures. The TEP should also consider whether risk adjustment strategies will be needed and if any exclusion criteria should be considered so that the measure is usable from both patients' and providers' perspectives.

TEP Requirements:

A TEP of approximately 11-20 individuals will brainstorm to develop one or more measure concepts that can be further developed to determine other aspects such as reliability and validity. The TEP will need to consider the current state of evidence to support any measure concept that is developed for consensus based entity (CBE) endorsement.

The TEP will be composed of individuals with differing areas of expertise and perspectives, including:

- Nephrology providers (physicians, advanced practice providers), nephrology trained social workers, dieticians, and dialysis facility nursing staff
- ESRD bone and mineral disorder experts
- Consumer/Patient/Family/Care Partner perspective
- Performance measurement experts
- Quality improvement experts
- Purchaser perspective
- Healthcare disparities experts

Scope of Responsibilities:

UM-KECC is seeking balanced representation of dialysis stakeholders and clinical experts representing patients, patient advocates, and dialysis providers as well as clinical, statistical, and public health experts to identify and evaluate one or more potential quality measures intended to evaluate mineral and bone disorder in dialysis patients. It is UM-KECC's intent to facilitate TEP discussion through presentation of background information (peer reviewed publications, guidelines, and related existing quality measures) that will set the context for new measure development. The TEP will be led by one or two Chairpersons, whose responsibility is to guide the discussion and attempt to develop consensus opinions from TEP membership regarding the topics described in the TEP Objectives section above. The TEP is intended to be advisory to UM-KECC, as UM-KECC continues to develop and refine the draft measure described in this document.

Role of UM-KECC: As the CMS measure developer contractor, UM-KECC has a responsibility to support the development of quality measures for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the review of draft measure specifications, as recommended by the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs, requirements, and timeline of the CMS contract, and may provide specific guidance and criteria that must be met with respect to CMS and CBE review of revised candidate measures reflecting prevalent comorbidities.

Role of TEP chair(s): Prior to the TEP meetings, one or two TEP members are designated as the chair(s) by the measure contractor and CMS. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding measure specifications.

Duties and Role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to review any existing measures, provide input as to data sources and feasibility, and to suggest measure specifications. TEP members are expected to attend conference calls in 2024 and be available for additional follow-up teleconferences and correspondence as needed to support the submission and review of the candidate measure(s) by the CBE. Some follow up activities may be needed after testing has occurred.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP and the goals/objectives of the ESRD Facility Level Measure Development

project will be described. TEP members will be provided with a summary of peer reviewed literature and other related quality measures. TEP members will have the opportunity to submit additional studies to be included in the literature review. A review of the CMS and CBE measure development criteria will also be covered during the teleconference.

During the TEP Meetings: The TEP will review evidence to determine the basis of support for proposed measure(s). The key deliverables of the TEP include:

- Recommending draft measure specifications
- Assisting in completing the necessary documentation forms to support submission of the measures to CMS for review, and to the CBE for endorsement
- As needed, TEP members may be asked to provide input to UM-KECC as they prepare responses to CBE and public comments

Following the TEP meetings, the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through any other issues. This will include votes for draft and final measures. TEP members will review a summary report of the TEP meeting discussions, recommendations, draft measure specifications, and other necessary documentation forms required for submission to the CBE for endorsement

Guiding Principles:

Participation as a TEP member is voluntary and the measure developer records the participant's input in the meeting minutes, which the measure developer will summarize in a report that they may disclose to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. TEP organizers will answer any questions about confidentiality.

The TEP will use both verbal consensus and formal voting by secret ballot for decision-making, depending on the context of the decision. For administrative and other decisions about agenda, direction of discussion, and other minor operational decisions, informal verbal consensus directed by the TEP chairs will be utilized. In order to objectively record TEP recommendations about the validity of the quality measures presented and recommended changes, formal votes utilizing secret ballot will be employed. These techniques have been used for nearly all clinical TEPs facilitated by the UM-KECC team over the last several years.

The measures evaluation standards included in the CMS Measures Blueprint and reflected in the CBE criteria are presented during an early TEP teleconference, typically during the first call. This is done so that TEP Charter approval and initial direction of the TEP discussion occur after TEP members are informed of the national consensus criteria that will ultimately be used to evaluate the quality measure(s) being considered by the TEP.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, there is no intent for the disclosure requirement to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to

inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

Estimated Number and Frequency of Meetings:

4-6 virtual meetings each being between 1 to 4 hours long. Meetings are tentatively scheduled for January – March 2024.

Date Approved by TEP:

TBD

TEP Membership:

TBD